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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,105	02/26/2001	Robert Shipman	VGEN.P-055	8468

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/14/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,105

Applicant(s)

SHIPMAN, ROBERT

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. The response to restriction (Paper No. 9) filed on July 15, 2002 has been entered.
2. Applicant's election with traverse of claim(s) 14 in Group II in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the amended claims do not lack of unity and the category X reference cited in International Search Report (Kapur et al.) is with respect to the claims not amended not applicable to the instant amended claims. This is found not persuasive because claims are grouped based on broadest claims as claim 1, the amendment of which did not change the scope of the claim. Both amended and not amended claim 1 refers to the method of identifying sequence variation, which category X reference anticipates. Hence claim 1 lacks special technical feature, which binds all other claims. Since Group I includes claim 1, lack of unity in this instant application is applicable. Further, Applicants argue that both Group I and Group II inventions share the same one or more primer sets and hence the lack of unity do not apply, which is found not persuasive because Group I is directed to method steps, whereas Group II is directed to a product. The method steps are not necessary to practice the invention in Group II. Therefore, the requirement is still deemed proper.
3. The disclosure is objected because of the following informalities:

In claim 14, SEQ ID Nos 1 and 2 are identical or duplicates of SEQ ID Nos. 3 and 4.

Correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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a. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim is indefinite and unclear because the instant claim recites “ at least one combination of primer pairs”, it is not clear whether the claim requires a primer pair (2 primers) or 2 primer pairs (4 primers). For prior art purposes, the 35 U.S.C. 102(b) rejection is based on the first interpretation of two primers and the U.S.C. 103(a) rejection is based on the second interpretation of four primers. Amendment of the claim to properly recite the limitation would obviate the rejection.

b. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim is indefinite and incomplete for being dependent on non-elected species.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by De Beenhouwer et al. (WO 95/33851).

As noted above in the rejection under U.S.C. 112, second paragraph, this rejection is based on the first interpretation of two primers.

De Beenhouwer et al. teach a set of primers in the form of a kit to evaluate antibiotic resistance spectrum of mycobacteria, wherein the instant SEQ ID Nos. 1 and 3 match with complete homology to the primer P2 of the disclosure of De Beenhouwer et al. (see page 55, lines 17-21, page 56, lines 10-22, and page 39, line 9 (primer P2) and see sequence alignment from Gene seq database). Thus the disclosure of De Beenhouwer et al. meets the limitations in the instant claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over De Beenhouwer et al. (WO 95/33851) and in view of Heym et al. (USPN. 5,851,763) and Foxall et al. (USPN. 5,985,569).

As noted above in the rejection under U.S.C. 112, second paragraph, this rejection is based on the second interpretation of four primers.

De Beenhouwer et al. teach a set of primers in the form of a kit to evaluate antibiotic resistance spectrum of mycobacteria, wherein the instant SEQ ID Nos. 1 and 3 match with complete homology to the primer P2 of the disclosure of De Beenhouwer et al. (see page 55, lines 17-21, page 56, lines 10-22, and page 39, line 9 (primer P2) and see sequence alignment from Gene seq database). However, DeBeenhouwer et al. did not teach SEQ ID Nos. 2 and 4.

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Heym et al. teach a method and a kit for detecting mutations in antibiotic resistance mycobacterium tuberculosis wherein Heym et al. teach primers are selected from rpoB gene sequence (SEQ ID No. 59) of mycobacterium tuberculosis, which comprises the instant claimed SEQ ID Nos. 2 and 4 with complete homology (see sequence alignment from issued patent database, and column 24, lines 8-13, lines 52-56, columns 85-86, SEQ ID NO. 59 and column 3, lines 35-41).

Foxall et al. teach designing mycobacterium genus-specific primers for polymerase chain reaction using a computer program, OLIGO-PROBE DESIGN STATION (see column 13, lines 30-61).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the sequences of primer as taught by De Beenhouwer et al. with the primer selection sequence as taught by Heym et al. and Foxall et al. which is well known in the art at the time the invention was made, because De Beenhouwer et al. states that "probes including species specific probes contained in the sequence of the rpoB gene are designed in such a way that they all can be used simultaneously, under the same hybridization conditions, which implies a single amplification and hybridization step is sufficient for simultaneous detection of rifampicin resistance and the identification of the mycobacterial species involved" (see page 16, lines 6-13). One such alternative form of sequence selection from rpoB gene, expressly motivated by Heym et al. is the design of primer sequence encompassed by rpoB gene.

Further, In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the

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court stated

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers simply represent structural homologs, which are suggested by the prior art as useful for primers and probes, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

An ordinary practitioner would have been motivated to combine the sequences of De Beenhouwer et al. with the primer sequences of Heym et al. and selection of primers of Foxall et al. in order to achieve the expected advantage of a sensitive kit composition for evaluating antibiotic resistance of mycobacterium species. Claim, which utilizes closed language that require the inclusion of primers 1-4 would overcome this rejection.

No claim is allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
August 9, 2002


JEFFREY FREDMAN
PRIMARY EXAMINER